

COMMITTEE ON HUMAN RESEARCH
INITIAL SHORT-FORM APPLICATION

PRINCIPAL INVESTIGATOR (UCSF Faculty)		University
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(Campus) <u>1001 Potrero Ave., SF, 94110</u>	<u>Number 821-5200</u>	<u>Advisor Only? No</u>
CO-PI.		University
(Name & Degree) <u>Neal Benowitz, M.D.</u>	<u>Title Prof. of Medicine</u>	<u>Dept. Medicine</u>
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(Campus) <u>1001 Potrero Ave., SF, 94110</u>	<u>Number 821-8324</u>	SUBMISSION
PROJECT		DATE 5 July 1990
TITLE <u>The Relationship of Tobacco Exposure to Semen Biomarkers</u>		

INSTRUCTIONS: Please submit five (5) identical, collated sets of the following:
THIS COMPLETED SHORT-FORM (both sides)
ALL CONSENT FORMS/INFORMATION SHEETS
ALL ATTACHMENTS (i.e., questionnaires, interview guides, support letters)

PLEASE NOTE: See PART V of the *UCSF Guidelines for Research Involving Human Subjects* (October 1987) for detailed information and directions on all of the above. It takes approximately 4 to 6 weeks to complete the review process of a CHR Initial Short-Form Application.

1. **STUDY AIM, BACKGROUND, AND DESIGN** The purpose of this study is to expand a larger, ongoing study to evaluate the relationship between active and passive smoke exposure to semen biomarkers. The larger study, the Men's Reproductive Health Study (MRHS), is being jointly conducted by the Calif. Dept. of Hlth. Serv. (CDHS), Kaiser Div. of Research, U.C., Davis and Lawrence Livermore Natl. Laboratory. The MRHS is a prospective, 5 year study (currently in year 3) that will follow "normal" couples at risk for pregnancy to determine the relationship between semen quality, reproductive outcomes and a number of environmental exposures. Women collect daily urine for 6 months which is assayed for hCG. Their male partners provide two semen samples by masturbation and a saliva sample. Both complete an extensive baseline interview. A component of the MRHS is to assay semen and saliva samples for nicotine and cotinine, then evaluate the relationship between these measures of exposure and semen biomarkers.

2. **SUBJECT POPULATION: INCLUSION/EXCLUSION CRITERIA, USE OF SPECIAL SUBJECT GROUPS, AND METHODS OF ACCESS**
Kaiser Division of Research is screening 6,000 subscribers to the Santa Clara Kaiser medical facility to identify eligible women who are willing to collect daily urine samples for six months. Eligibility criteria for women are: (1) age 18 to 39, (2) no unprotected intercourse for greater than 3 months with current partner, (3) neither she nor her partner have been sterilized, (4) not using oral contraceptives or an intrauterine device, (5) not amenorrheic or hysterectomized, and (6) not pregnant in the past six months. All male partners of participating women will be contacted by telephone for recruitment.

3. **PROCEDURES TO BE DONE FOR PURPOSES OF THE STUDY**
Saliva samples and semen samples will be assayed by gas chromatography-mass spectroscopy for nicotine and cotinine concentrations.

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4. RISKS: POTENTIAL RISKS, INCLUDING POSSIBLE LOSS OF CONFIDENTIALITY, AND DISCOMFORTS TO SUBJECTS. METHODS OF MINIMIZING THESE RISKS

There are no known physical risks to participating subjects and the procedures are not uncomfortable. There may be some psychological or social harm to subjects if the confidentiality of their participation was compromised. To prevent this, all samples and data received will be marked only with human subject numbers (HSN), no personal identifying information. The code is maintained by the Human Division of Research. Database created will be identified only by the HSN and will contain personal identifiers.

5. BENEFITS: POTENTIAL DIRECT BENEFITS TO SUBJECTS AND GENERAL BENEFITS TO SUBJECT GROUP, MEDICAL SCIENCE AND/OR SOCIETY

There is no direct benefit to subjects. Medical science and society may benefit with insight into the effect of active and passive tobacco smoke exposure on measures of male reproductive function.

6. CONSENT PROCESS AND DOCUMENTATION

Human subjects approval for the MRHS was received from the Kaiser Permanente Institutional Review Board on December 19, 1989. A copy of the approval and the consent form is attached.

7. NUMBER OF SUBJECTS TO BE ENROLLED PER YEAR:

TOTAL FOR STUDY:

 (5/90 to 6/91)

8. WILL THIS STUDY BE FUNDED? ☒ Yes ☐ No ☐ Pending

FUNDING SOURCE: ☐ Federal ☒ Other

AGENCY/SPONSOR: Tobacco-Related Research Program

9. EXPEDITED REVIEW CATEGORY NUMBER 2.11 (from PART V-B of the UCSF Guidelines for Research Involving Human Subjects, October 1987)

10. PRINCIPAL-INVESTIGATOR'S SIGNATURE

Daniel Rengel

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